Preferred Drug List Committee Meeting

Meeting Minutes, Open Session
March 13, 2019 11:30 a.m. to 1pm
DXC Technologies-Capital Room, 6511 SE Forbes Ave., Bldg. 283 J, Topeka, Kansas 66619

Board Members Present:
Jessica Bates, PharmD, BCPS
Taylor Gill, PharmD, BCPS (Interim Chair)
Robert Haneke, PharmD (by Phone)
Raymond Magee, M.D. (by Phone)
Donna Sweet, M.D. (by Phone)
Wayne Wallace, M.D.

Board Members Absent:
Megan Hedden PharmD

KDHE-DHCF Staff:
Annette Grant, RPh.
Victor Nguyen, PharmD
Margaret O'Donnell, Transcriptionist

DXC/HID Staff Present:
Karen Kluczykowski, RPh.
Kathy Kaesewurm, R.N., BSN

MCOs Present:
Angie Zhou, PharmD, Sunflower State Health Plan
Jennifer Murff, RPh, UnitedHealthcare Community Plan
Alan Carter, PharmD, Aetna Better Health of Kansas

Public Attendees:
Emma Fletcher, Kyle Regenold, Miranda Diec, Melissa Hinlichsen, KU Pharmacy School; Porscha Showers, Eli Lilly; Chris Stanfield, Supernus; Laura Hill, Melissa Basil, AbbVie; Deron Grothe, Chad Palodichuk, Teva; Jim Baumann, Pfizer; Camille Kerr, Amgen; Tami Oberheim, Thao Hoang, KDHE
*Illegible names on the sign-in sheet were not included.

Item	Notes
I. Call to Order	Dr. Gill (Interim Chairperson) called the March 13, 2019 PDL Committee meeting to order at 11:33 a.m. Dr. Gill requested introductions from all those present at the table and notified the public attendees about the rules of public comment. She also requested that if anyone wishes to make a public comment, they must fill out and turn in to her the Conflict of Interest Form prior to speaking.
II. Old Business **1. Review and Approval of June 13, 2018 Meeting Minutes.**	The draft minutes from the June 13, 2018 meeting were reviewed. Dr. Sweet moved to approve the minutes. Dr. Wallace seconded the motion. The motion carried unanimously, and the minutes were approved.
2. Review and Approval of September 12, 2018 Meeting Minutes.	The draft minutes from the September 12, 2018 meeting were reviewed. Dr. Sweet moved to approve the minutes. Dr. Haneke seconded the motion. The motion carried unanimously, and the minutes were approved**.**
3. Consent Agenda Items **i. PDL New Drug Placements** 1. Axid® Solution 2. Evekeo® ODT 3. Fycompa Suspension 4. Gabapentin Solution 5. Methylin® ER Tablets 6. Novolin®70/30 Flexpen™ 7. Onfi® Suspension 8. Tagamet® Solution 9. Zantac® Capsules 10. Zantac® Solution	**Background:** At the September 13, 2017 PDL meeting, the Committee agreed to the "Consent Agenda Items" pre-management process and to place the associated drug list under the Old Business section. **Public Comment:** None. **Board Discussion:** Dr. Wallace moved to approve. Dr. Sweet seconded the motion. The motion carried unanimously.

Item	Notes
III. New Business **1. Expanded Consent Agenda -Additional Pre-approval Request Criteria**	**Background:** Proposal to add additional pre-management criteria to the current Consent Agenda List criteria. Additional criteria: a. If the new drug is a racemic mixture, a single enantiomer, diastereomer, or isomer of a current PDL drug. b. Or, the new drug is a prodrug of a current PDL drug. c. Or, the new drug includes the active ingredient moiety of a current PDL drug in the same PDL class/category but differs by brand name or manufacturer. **Public Comment:** Jim Baumann with Pfizer asked if combination drugs would be included. The State responded that they would not be included in the Expanded Consent Agenda unless there is a combination of the same already in the class. **Committee Discussion:** Dr. Magee moved to approve. Dr. Sweet seconded the motion. The motion carried unanimously.
2. Adjunct Anti-epileptics – Class Review – New Agent: (Sympazan™)	**Background:** Adjunct anti-epileptics were introduced as a new class 2006. The last review was March of 2017 for the inclusion of Lyrica® & Keppra® oral solutions. This proposition is to request the inclusion of Sympazan™, a film formulation of clobazam. Coming in either 5mg or 10mg strengths, Sympazan™ is indicated as adjunct therapy for Lennox-Gastaut and Dravet syndromes **Public Comment:** None **Committee Discussion:** Dr. Wallace moved to approve. Dr. Bates seconded the motion. The motion carried unanimously.

Item	Notes
III. New Business (continued) **3. Androgenic Agents – Class Review - New Agent: (Xyosted™)**	**Background:** Androgenic agents, as a class, were last reviewed in September of 2017. This proposition is to request the inclusion of Xyosted™, a weekly subcutaneous delivery system of testosterone enanthate. Using the disposable QuickShot® injector, the testosterone enanthate is presented in an easy-to-use method capable of home administration. Xyosted™ comes in 50mg, 75mg, and 100mg per injection and is indicated for male hypogonadism. **Public Comment:** None. **Committee Discussion:** Dr. Wallace moved to approve. Dr. Haneke seconded the motion. The motion carried unanimously.
4. Anticholinergics for the Maintenance Treatment of COPD-Class Review - New Agent- (Yupelri™)	**Background:** Anticholinergics for the Maintenance Treatment of COPD were introduced as a new class in 2013. The last review was March of 2018 for the inclusion of Lonhala™ Magnair™ (glycopyrrolate). This proposition is to request the inclusion of Yupelri® a, first-of-its-kind, nebulizer solution of revefenacin. Used as an anticholinergic for the maintenance treatment of chronic obstructive pulmonary disease, Yupelri® comes in 175mcg unit-dose vials. **Public Comment:** None. **Committee Discussion:** Dr. Wallace moved to approve. Ms. Bates seconded the motion. The motion carried unanimously.

Item	Notes
III. New Business (continued) **5. Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonists – New Class: (Aimovig™, Ajovy®, Emgality®)**	**Background:** The calcitonin gene-related peptide (CGRP) receptor antagonist class is presented today for approval and inclusion to the PDL. These biologics work as human monoclonal antibodies that bind to the calcitonin gene-related peptide ligand and block its binding to the receptor. Although the exact mechanism of the calcitonin gene-related peptide receptor is unknown, these products are indicated for migraine prophylaxis. **Public Comment:** Porscha Showers with Eli Lilly presented on Emgality®. **Committee Discussion:** Dr. Wallace moved to approve. Ms. Bates seconded the motion. The motion carried unanimously.
6. Corticosteroids – Ophthalmic – New Class: (Maxidex®, Durezol®, Flarex®, FML® (Susp./Liquifilm®/Oint./Forte), Lotemax® (Gel/Susp./Oint.), Alrex®, Omnipred®, Pred Forte®, Pred Mild®)	**Background:** The Corticosteroids – Ophthalmic class is presented today for the approval and inclusion to the PDL. These agents reduce inflammation by inhibiting edema, leukocyte migration, fibrin deposition, capillary proliferation and dilation, collagen deposition and scar formation. **Public Comment:** None. **Committee Discussion:** The board discussed whether to have one general class of ophthalmic corticosteroids or two classes of corticosteroids based primarily upon post-operative indication versus general inflammatory use. The decision was to keep as one general class of ophthalmic corticosteroids. Dr. Wallace moved to approve. Dr. Magee seconded the motion. The motion carried unanimously.

Item	Notes
III. New Business (continued) **7. Corticosteroids - Topical – High Potency – Class Review – New Agent: (Bryhali™)**	**Background:** High potency topical corticosteroids were introduced as a class September 2017 with June of 2018 being the last review. This proposition is to request the inclusion of Bryhali™ which is a 0.01% halobetasol propionate-based lotion approved by the FDA early November 2018. With the anti-inflammatory, antipruritic, and vasoconstrictive properties that reduce the activity of inflammation mediators, Bryhali™ is indicated for the treatment of plaque psoriasis. As Bryhali™ uses a novel vehicle, safety of the high potency corticosteroid has been established surpassing the standard two weeks and reaching up to eight weeks with no increase in epidermal atrophy. **Public Comment:** None. **Committee Discussion:** Dr. Wallace moved to approve. Ms. Bates seconded the motion. The motion carried unanimously.
8. Leukotriene Receptor Antagonists – New Class: (Accolate®, Singulair®, Zyflo®, Zyflo CR®)	**Background:** The leukotriene receptor antagonist class is presented today for the approval and inclusion to the PDL. These agents act as selective antagonists at the leukotriene receptors resulting in relief of airway edema, smooth muscle contraction and inflammation. This predominately leads to relief of asthma-related symptoms. **Public Comment:** None. **Committee Discussion:** The State informed the committee that the name of the class from Leukotriene Receptor Antagonists to Leukotriene Receptor Modifiers was done after the documents were emailed to the board for pre-review. Dr. Wallace moved to approve with the title as presented at the meeting.

	Dr. Magee seconded the motion. The motion was approved with the class name, as presented at the meeting.

Item	Notes
III. New Business (continued) **9. Prostaglandin Analogs – Class Review – New Agent: (Xelpros™)**	**Background:** Prostaglandin analogs were introduced as a class in 2005 with March of 2018 being the last review. This proposition is to request the inclusion of Xelpros™, which is a 0.005% emulsion of latanoprost. Indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension, this latanoprost-based product is the first to be formulated without the preservative benzalkonium chloride. **Public Comment:** None. **Committee Discussion:** Dr. Wallace moved to approve. Dr. Haneke seconded the motion. The motion carried unanimously
IV. Open Public Comment	None.
V. Adjourn	Dr. Sweet moved to adjourn. Dr. Bates seconded the motion. Dr. Gill adjourned the meeting at 12:10 p.m.

March 2019 Consent Agenda Item List				
This PDL option/process was approved 09/13/2017 by the PDL Committee and 10/11/2017 by the DUR Board.				
Drug Proposed - Consent Agenda Item	**Compare Drug**	**Supporting information**	**Meeting Date listed on the PDL Agenda**	**PDL Committee Approval Yes/No**
Axid® Solution	Axid® Capsule		3/13/2019	
Eveko® ODT	Evekeo®		3/13/2019	
Fycompa Suspension	Fycompa Tablets		3/13/2019	
Gabapentin Solution	Gabapentin Caps/Tabs		3/13/2019	
5Methylin® ER Tabs	Methylin® Chewables		3/13/2019	
Novolin® 70/30 Flexpen™	Novolin® 70/30 vial		3/13/2019	
Onfi® Suspension	Onfi® Tablets		3/13/2019	
Tagamet® Solution	Tagamet® Tablets		3/13/2019	
Zantac® Capsules	Zantac® Tablets		3/13/2019	
Zantac® Solution	Zantac® Tablets		3/13/2019	